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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,591

08/19/2003

Takaaki Isshiki

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EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

03/13/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/642,591	<b>Applicant(s)</b> ISSHIKI ET AL.	
	<b>Examiner</b> JING RUI OU	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is responsive to the amendment filed on November 21, 2007. Claims 1-8 are pending. Claim 1 is independent. Claim 2 is cancelled.

Claims 1, 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116). Khosravi discloses sheath (the portion of sheath 52 which has the enlarged distal region of lumen 64 as described in col. 5, lines 19-22) being closed at the proximal end (by the narrow proximal region described in col. 5, lines 19-25), a flexible shaft (the combination of shaft 12 and member 54 which is attached thereto as indicated in col. 5, lines 32-35, and noting that shaft 12 is flexible in the embodiment described in col. 4, lines 13-16 due to the articulations therein), the flexible shaft being a wire member (Shaft 12 and attached member 54 together are a "wire" member since this member is very thin, as indicated in col. 5, lines 39-42, and elongated. The fact that the member has a passageway through it does not preclude it from being a wire. For example, some guide wires have an elongated passageway through them for fluid delivery. Yet, they are wires.), thrombus capture member 14, 16 comprising a plurality of wires 24 forming a frame and having a configuration swollen in the middle portion and mounted slidably on shaft 12 at the distal end but fixed on the shaft at the proximal end thereof (col. 4, lines 24-27). Khosravi fails to disclose the filter frame wires 24 as being spiral and crossed with one another. However, Brooks et al. teach that filter frame wires 56 for supporting an endovascular filter membrane should be spiral and crossed with one another (col. 4, lines 37-43) apparently in order to obtain the advantage of better

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supporting the filter membrane around its circumference. It would have been obvious to make the Khosravi filter frame wires 24 spiral and crossed with one another so that it too would have this advantage. As to claim 4, Khosravi fails to disclose a hemostatic valve and a tubular member to hold it. However, it is old and well known to use hemostatic valves and tubular members to hold them in surgical devices in order to obtain the advantage of preventing blood loss. It would have been obvious to include a hemostatic valve and tubular member to hold it in the Khosravi device so that it too would have this advantage. The proximal portion of shaft 12 of Khosravi protrudes from the sheath 52 when the shaft 12 is inserted therein as described in col. 5, lines 51-56. As to claim 7, Khosravi fails to disclose the slide ring assembly as comprising an inner ring and an outer ring with the wires sandwiched therebetween. However, it is old and well known in this art to secure wires between inner and outer rings in order to obtain the advantage of providing a strong attachment between the wires and ring assembly. It would have been obvious to so construct the sliding ring in the Khosravi device so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (6,361,546) in view of Brooks et al. (6,346,116) as applied to claim 1 above, and further in view of Rosenbluth (WO 99/56801). As to claim 5, Khosravi fails to disclose a side hole and second lumen in the sheath. However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side hole 310 and second

lumen 309 in order to obtain the advantage of permitting rapid exchange of the sheath (page 18, lines 13-22). It would have been obvious to include a side hole and second lumen in the Khosravi sheath so that it too would have this advantage. As to claim 6, Khosravi fails to disclose a side infusion tube. However, Rosenbluth teaches that a sheath 11 for an intravascular filter should include a side infusion port 15 attached thereto in order to obtain the advantage of permitting injection of contrast medium into the vessel (page 15, lines 15-24). It would have been obvious to include a side infusion port in the Khosravi device so that it too would have this advantage.

### ***Response to Arguments***

Applicant's arguments filed 11/21/2007 have been fully considered but they are not persuasive.

The allegation on page 6 of the remarks that Khosravi fails to disclose a flexible shaft (combination of shaft 12 and member 54) that serve as a guide wire is incorrect. The embodiment described in col. 4, lines 2-10 clearly stated that the shaft 12 being sufficiently short can serve as a guide wire by facilitating introduction into and advancement along a body blood vessel. Therefore, Khosravi's the combination of shaft 12 and member 54 has the same function as the flexible shaft of the present invention. In addition, the wire 24 is fixed at their proximal ends to the flexible shaft and the flexible shaft remains within the blood vessel during treatment.

The allegation on page 7 of the remarks that the present invention is never obvious from Khosravi since the present invention does not require an independent retrieval device as the thrombus capture member is provided on the distal end of the

flexible shaft which serves as a guide wire. In Claim 1, Khosravi only fails to disclose the filter frame wires 24 as being spiral and crossed with one another. However, Brooks et al. teach that filter frame wires 56 for supporting an endovascular filter membrane should be spiral and crossed with one another (col. 4, lines 37-43) apparently in order to obtain the advantage of better supporting the filter membrane around its circumference. It would have been obvious to make the Khosravi filter frame wires 24 spiral and crossed with one another so that it too would have this advantage. Therefore, it would not make the present invention non-obvious by not require such an independent retrieval device.

In response to applicant's argument stated on page 8 of the remarks that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the spiral wires of the present invention are never braided together to allow them to move freely without being restricted to each other) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING RUI OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JRO

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773